PMA Decisions Rendered for July 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
PMA Original Approvals			
P060002 **7/23/07**	FLAIR™ Endovascular Stent Graft	Bard Peripheral Vascular, Inc. Tempe , AZ 85280	Approval for the FLAIR™ Endovascular Stent Graft. The device is indicated for use in the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous (AV) access grafts.
PMA Supplemental Approvals			
P870072/S036 **7/27/07** **Real-Time**	Thoratec Implantable Ventricular Assist Device (IVAD) System	Thoratec Corporation Pleasanton , CA 94588	Approval for a change in the design of the Thoratec Implantable Ventricular Assist Device System's pneumatic line.
P880086/S150 **7/12/07** **Real-Time**	St. Jude Medical Identity and Identity ADx Family of Devices	St. Jude Medical Cardiac Rhythm Management Division Sylmar , CA 91342	Approval for use of the circuitry use din the analog chip in the Victory/Zephyr family of devices in the analog chip used in the Identity and Identity ADx family of devices, and for resizing the Sense and IEGM gain capacitors.
P910023/S142 **7/10/07** **Real-Time**	Cadence® Tiered-Therapy Defibrillator System	St. Jude Medical Cardiac Rhythm Management Division Sunnyvale , CA 94086	Approval for software modifications to the Housecall Plus System software (Receiver Software Model 4000 Version 3.1) which merges the HouseCall receiver 3.0.3 and the Matrix PCS 2.0 software version.
P920015/S037 **7/3/07** **Real-Time**	Sprint Fidelis Lead Models 6949, 6948, 6931, and 6930	Medtronic, Inc. Shoreview , MN 55126	Approval for design and manufacturing changes to improve the DF-1 leg strength and handling characteristics of Sprint Fidelis leads.
P990001/S028 **7/10/07** **Real-Time**	Vitatron C-series (A1 models), Vitatron C-Series (A3 models), Vitatron T-Series, and Vitatron Diva, DEMA, and selection AFm Devices	Medtronic Cardiac Rhythm Disease Management Shoreview , MN	Approval for modifications to the Vitatron family application software models that support the Diva, DEMA and Selection AFm 902 devices (VSC02 version 9.1 SR1), C-series devices A1 models (VSF04 version 1.3), C-series devices A3 models (VSF12 version 1.2, and T-series devices (VSF08 version 1.6). The modifications will update the EMI behavior of your device, correct the issue of DA+ inhibition of pacing below the programmed threshold, identify to the user inaccurate coulomb counts, allow the application suite to be split into several application packages, and minor software enhancements.

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APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P020018/S024 **7/5/07** **180-Day**	36 mm Diameter Zenith® AAA Endovascular Graft/Zenith® Renu™ AAA Ancillary Graft	Cook, Inc. Bloomington , IN 47402	Approval to market the 36 mm Diameter Zenith® AAA Endovascular Graft/Zenith® Renu™ AAA Ancillary Graft
P030047/S003 **7/12/07** **180-Day**	Cordis PRECISE® OTW 5.5 Fr and 6.0 Fr Nitinol Stent System	Cordis Corporation Warren , NJ 07059	Approval for the Cordis PRECISE® PRO Rx Nitinol Stent System.
P030054/S049 **7/25/07** **180-Day**	QuickFlex™ Model 1156T and XL Model 1158T Left Ventricular Pacing Leads	St. Jude Medical CRMD Sylmar , CA 91342	Approval for distal tip modifications to the QuickSite lead family to reduce the length of rigid sections and increase lead flexibility. The device, as modified, will be marketed under the trade name QuickFlex Model 1156T and XL Model 1158T Left Ventricular Pacing Leads. QuickFlex leads are 6 French, transvenous, steroid eluting, bipolar, IS-1 compatible, S-shaped curve, passive fixation leads intended for permanent sensing and pacing of the left ventricle when used with a compatible St. Jude Medical's biventricular system.
P050007/S006 **7/30/07** **Real-Time**	StarClose™ and StarClose™ SE Vascular Closure Systems	Abbott Vascular Devices Redwood City , CA 94063	Approval for design changes to the Pusher Body for both the StarClose™ Vascular Closure System (VCS) and the StarClose™ SE Vascular Closure System ad for the addition of chambers on the interior of the StarClose™ SE Vascular Closure System to improve the retraction of the Thumb Advancer.